TERMS OF DEGREE NOT NEC. INDEFINITE "SUBSTANTIAL"

FULL TEXT OF CASES (USPQ2D)
All Other Cases
Bausch & Lomb Inc. v. Alcon Laboratories Inc. (DC WNY) 53 USPQ2d 1353 (12/22/1999)

Bausch & Lomb Inc. v. Alcon Laboratories Inc. (DC WNY) 53 USPQ2d 1353

Bausch & Lomb Inc. v. Alcon Laboratories Inc.

U.S. District Court Western District of New York
53 USPQ2d 1353

Decided December 22, 1999
No. 94-CV-6534L

Headnotes

EX PARTE OETIKER 23USPQ2d 1641 (Bd. PAT APP & Inter. 1992)

PATENTS

1. Patentability/Validity -- Specification -- Claim adequacy (§ 115.1109)

Use of imprecise language does not automatically render patent claim invalid, nor does 35 U.S.C. Section 112 require that claims be made as precise as humanly possible, since degree of precision with which claims must be stated to meet definiteness requirement is function of nature of subject matter, and since amount of detail required thus depends upon particular invention and prior art, and must not be viewed in abstract; therefore, if term of degree, such as "substantially," is used in claim, district court must determine whether specification provides some standard for measuring that degree, such that person of ordinary skill in art would understand what is claimed.

2. Patentability/Validity -- Specification -- Claim adequacy (§ 115.1109)

Claims for method of simultaneously cleaning and disinfecting contact lenses, in which presence of cleaning enzymes does not "substantially inhibit" effectiveness of disinfectant in cleansing solution, will not be held indefinite, even though term "substantially" does not convey quantifiable standard, since, in context of microbiology, term is understood to mean "microbiologically significant," which would be interpreted by person of ordinary skill in art to refer to particular calculable range of reduction in antimicrobial activity.

3. Patentability/Validity -- Specification -- Claim adequacy (§ 115.1109)

Claims for method of simultaneously cleaning and disinfecting contact lenses, in which presence of cleaning enzymes does not "substantially inhibit" effectiveness of disinfectant in cleansing solution, embodies requirement, in U.S. Food and Drug Administration guidelines, that changes in solution "not adversely affect" performance of solution, in view of evidence that person of ordinary skill in microbiology would interpret "substantially inhibit" to refer to particular calculable range of reduction in antimicrobial activity, since person of ordinary skill would know solution was intended for commercial production that would require FDA approval.

4. Patentability/Validity -- Specification -- Claim adequacy (§ 115.1109)

Accused infringer has failed to meet its burden of showing, by clear and convincing evidence, that claims for method of simultaneously cleaning and disinfecting contact lenses, in which presence of cleaning enzymes does not "substantially inhibit" effectiveness of disinfectant in cleansing solution, are invalid for indefiniteness under 35 U.S.C. Section 112, since terms "substantial" and "substantially" are not uncommon in contact lens industry patents, including some for

which defendant's witness was named as inventor.

5. Patentability/Validity -- Specification -- Claim adequacy (§ 115.1109)

JUDICIAL PRACTICE AND PROCEDURE

Procedure -- Evidence -- Expert testimony (§ 410.3703)

Alleged inconsistencies in statements by infringement plaintiff's experts do not warrant finding that patent claims for method of simultaneously cleaning and disinfecting contact lenses, in which presence of cleaning enzymes does not "substantially inhibit" effectiveness of disinfectant in cleansing solution, are invalid for indefiniteness under 35 U.S.C. Section 112, since fact that experts, at various times, used different words to explain understanding of "does not substantially inhibit" does not constitute contradiction, and since alleged inconsistencies are insubstantial and taken out of context.

PATENTS

6. Patentability/Validity -- Specification -- Claim adequacy (§ 115.1109)

Claims for method of simultaneously cleaning and disinfecting contact lenses, in which presence of cleaning enzymes does not "substantially inhibit" effectiveness of disinfectant in cleansing solution, will not be held indefinite, even though documents submitted by infringement plaintiff to foreign patent office contain actual numerical values instead of term of degree "substantially inhibit," since fact that patentee could express claim in numerical terms does not require that claim be thus expressed.

Particular patents -- Chemical -- Contact lens cleaning solution

5,096,607, Mowrey-McKee, Proud, and Minno, method for cleaning and disinfecting contact lenses, not invalid.

Case History and Disposition:

Action by Bausch & Lomb Inc. against Alcon Laboratories Inc. for patent infringement. Following order denying summary judgment of invalidity in favor of defendant (52 USPQ2d 1385), district court conducted evidentiary hearing on issue of indefiniteness. On defendant's request for entry of judgment that claims of plaintiff's patent are invalid for indefiniteness. Denied.

Attorneys:

Michael Wolford, of Wolford & Leclair, Rochester, N.Y.; Denis A. Polyn and Jill K. Schultz, of Bausch & Lomb, Rochester, N.Y.; Robert L. Baechtold, Scott K. Reed,Steven C. Kline, Dominick A. Conde, Gregory B. Sephton, and Daniel R. Cahoy, of Fitzpatrick, Cella, Harper & Scinto, New York, N.Y., for plaintiff.

William L. Dorr, of Harris, Beach & Wilcox, Rochester, N.Y.; W. Edward Bailey, Kevin J. Culligan, A. Peter Adler, Elizabeth Schuler, and Charles A. Krauss, of Fish & Neave, New York, N.Y., for defendant.

Opinion Text

Opinion By:

Larimer, C.J.

INTRODUCTION

This is a patent infringement action brought by Bausch & Lomb Incorporated ("B & L") against Alcon Laboratories, Inc. ("Alcon"). B & L alleges that Alcon has infringed on United States Patent No. 5,096,607 ("the '607 patent"), which claims an invention in a process for simultaneously cleaning and disinfecting contact lenses using a single solution.

On September 16, 1999, this court issued a Decision and Order that, *inter alia,* denied Alcon's Motion for Summary Judgment of Indefiniteness. *See Bausch & Lomb Inc. v. Alcon Labs., Inc.,* 64 F.Supp.2d 233 [52 USPQ2d 1385] (W.D.N.Y. 1999). In its motion, Alcon asserted that the statement in one of the claims of the '607 patent that its method for simultaneously cleaning and disinfecting contact lenses "does not substantially inhibit the activity of the antimicrobial agent" rendered the '607 patent indefinite because the patent does not explicitly define the phrase "does not substantially inhibit," nor does it set forth any objective, quantifiable parameters by which one could determine whether the activity of an antimicrobial agent has been "substantially inhibited."

In my September 16 Decision and Order, familiarity with which is assumed, I found that issues of fact existed regarding whether the '607 patent is indefinite, and therefore not in compliance with the requirements of 35 U.S.C. Section 112 Para. 2, which states that " [t]he specification shall conclude

with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." In particular, I noted that Alcon had not submitted any expert testimony of its own, but instead relied almost entirely on alleged inconsistencies and contradictions in the testimony of B & L's expert, Dr. Barbara Iglewski. I therefore denied Alcon's motion for summary

judgment, but set the matter down for an evidentiary hearing at which the court would take testimony and consider evidence regarding the issue of indefiniteness.

That hearing commenced on November 15, 1999, and ended on November 18. In addition to hearing live testimony at the hearing, the court has also read portions of deposition excerpts of a number of witnesses that had been designated by the parties, and has reviewed the documentary evidence submitted by both sides. This Decision and Order, then, constitutes my ruling on the issue of whether the '607 patent is sufficiently definite to meet the requirements of Section 112.

DISCUSSION

I. General Standards

The standards relating to Section 112's definiteness requirement have been set forth in my September 16 Decision and Order, but bear repeating here. In short, patent claims must be sufficiently clear to allow one skilled in the art to understand what is claimed. *Amgen, Inc. v. Chugai Pharm. Co.,* 927 F.2d 1200, 1217 [18 USPQ2d 1016] (Fed. Cir.), *cert. denied* , 502 U.S. 856 (1991). Where the claims do not "have a clear and definite meaning when construed in the light of the complete patent document," the patent is rendered invalid. *Miles Labs., Inc. v. Shandon Inc.* , 997 F.2d 870, 874-75 [27 USPQ2d 1123] (Fed. Cir. 1993), *cert. denied* , 510 U.S. 1100 (1994).

The definiteness requirement serves two purposes. First, by clearly pointing out and distinctly claiming an invention, the claim alerts the public to what the patentee has claimed, so that potential infringers will be on notice of what might constitute infringement. Second, such a claim "makes clear any distinction that is supposed to exist between the patent and the prior art-- *i.e.* , it explains why the invention is novel." *Aluminum Co. of America v. Reynolds Metals Co.* , No. 88 C 6019, 1989 WL 165064 *4 [14 USPQ2d 1170] (N.D.Ill. Dec. 21, 1989). *See also United Carbon Co. v. Binney & Smith Co.* , 317 U.S. 228, 236 (1942); *In re Vamco Mach. and Tool Inc.* , 752 F.2d 1564, 1577 n.5 [224 USPQ 617] (Fed. Cir. 1985).

Citing *Amgen* , Alcon takes the position that a claim must be as precise as the subject matter permits. The court in *Amgen* did state that " [c]laims must . . . be 'as precise 'as the subject matter permits.' " 927 F.2d at 1217. That statement, however, was contained in a parenthetical characterization of the holding in *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.,* 758 F.2d 613 [225 USPQ 634] (Fed. Cir.), *cert. denied,* 474 U.S. 976 (1985)), but the court in *Shatterproof Glass* did not actually state that claims *must* be as precise as the subject matter permits. Rather, the court there stated that " [i]f the claims, read in the light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, *the courts can demand no more.* ' " *Id.* at 624 (quoting *Georgia-Pacific Corp. v. United States Plywood Corp.* , 258 F.2d 124, 136 [118 USPQ 122] (2d Cir.), *cert. denied,* 358 U.S. 884 (1958)) (emphasis added).

Were these the only two cases on the issue, there might be some ambiguity as to whether being as precise as the subject matter permits is a necessary, or merely a sufficient, condition for a claim to pass muster under Section 112. Federal Circuit cases do not insist on the kind of precision urged by Alcon. The Federal Circuit has never said that all claims must be made as precise as humanly possible, without exception. In fact, in a case decided after *Amgen,* the court observed that " [c]laims are often drafted using terminology that is not as precise or specific as it might be. As long as the result complies with the statutory requirement to 'particularly point[ ] out and distinctly claim [ ] the subject matter which the

applicant regards as his invention,' 35 U.S.C. Section 112, para. 2, that practice is permissible." *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1355 [48 USPQ2d 1351] (Fed. Cir. 1998).
The focus, then, is whether, given the nature of the subject matter, the claim is precise enough to make clear to a person skilled in the art what is claimed. There may be times when, for one reason or another, it is impossible, unnecessary, or undesirable to state a claim in terms of precise, quantified measurements. *See, e.g., United States v. Telectronics, Inc.*, 857 F.2d 778, 786 [8 USPQ2d 1217] (Fed. Cir. 1988) (district court erred as a matter of law in holding that if claim were read to mean that electric current must be applied "so as to minimize fibrous tissue formation," it would be invalid under Section 112 because it would be "impossible to determine when sufficient minimization takes place to determine what current range is involved"), *cert. denied,* 490 U.S. 1046 (1989). That is permissible as long as the dictates of Section 112 are met.
In addition, as noted in my September 16, 1999 Decision and Order, "the law is clear that the use of terms of degree, such as 'substantially,' in patent claims does not necessarily

render the claims indefinite. In fact, the Court of Appeals for the Federal Circuit has recognized that such 'words are ubiquitous in patent claims.' " *Bausch & Lomb,* 64 F.Supp.2d at 240 (quoting *Andrew Corp. v. Gabriel Electronics, Inc.*, 847 F.2d 819, 821 [6 USPQ2d 2010] (Fed. Cir.) (referring to, *inter alia,* phrase "substantially equal"), *cert. denied,* 488 U.S. 927 (1988)); *see also Amtel Corp. v. Information Storage Devices, Inc.*, 997 F.Supp. 1210, 1228 (N.D.Cal. 1998) (holding term "substantially all" not to be indefinite); *Pave Tech, Inc. v. Snap Edge Corp.*, 952 F.Supp. 1284, 1292 (N.D.Ill. 1997) (term "substantial," when considered in light of entire claimed invention, was as accurate as subject matter permitted, and provided sufficient guidance to one skilled in the art); *James River Corp. of Virginia v. Hallmark Cards,* 915 F.Supp. 968, 989 (E.D.Wisc. 1996) (word "substantially" in term "substantially integrated" was sufficiently defined, since one skilled in the art could recognize the difference between prior art and the claimed invention); *BOC Health Care, Inc. v. Nellcor Corp.*, 892 F.Supp. 598, 613 (D.Del. 1995) (finding phrase "substantially planar" to be sufficiently defined to those skilled in the art to avoid invalidity), *aff'd,* 98 F.3d 1357 (Fed. Cir. 1996); *Tuff Torq Corp.*, 1994 WL 827767 *12-13 (denying motion for summary judgment of indefiniteness with respect to term "substantially level"). Therefore, " [t]hat some claim language may not be precise . . . does not automatically render a claim invalid." *Seattle Box Co.*, 731 F.2d at 826. 1
[1] "Precision" should also not be equated with quantification. Not every claim must be expressed in terms of specific numerical values; rather, the degree of precision with which the claims must be stated to meet the definiteness requirement "is a function of the nature of the subject matter." *Miles Labs.*, 997 F.2d at 875. Thus, " [t]he amount of detail required to be included in claims depends on the particular invention and prior art, and is not to be viewed in the abstract . . .," but in conjunction with the specifications of the patent. *Shatterproof Glass,* 758 F.2d at 624. Accordingly, " [t]hat some claim language may not be precise . . . does not automatically render a claim invalid. When a word of degree is used the district court must determine whether the patent's specification provides some standard for measuring that degree," such that a person of ordinary skill in the art would understand what is claimed. *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 826 [221 USPQ 568] (Fed. Cir. 1984). In a similar vein, the Federal Circuit has cautioned that " [m]athematical precision should not be imposed for its own sake; a patentee has the right to claim the invention in terms that would be understood by persons of skill in the field of the invention." *Modine Mfg. Co. v. United States Int'l Trade Comm'n,* 75 F.3d 1545, 1557 [37 USPQ2d 1609] (Fed. Cir.), *cert. denied,* 518 U.S. 1005 (1996). *See also Telectronics,* 857 F.2d at 786 ("Section 112, Para. 2, requires only reasonable precision in delineating the bounds of the claimed invention").
Whether a patent claim is sufficiently definite is a question of law for the court to decide. *Morton Int'l. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1469 [28 USPQ2d 1190] (Fed. Cir. 1993). In making that determination, the court must be mindful that 35 U.S.C. Section 282 mandates that a "patent shall be

presumed valid," and that "the burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting it." In order to carry that burden, a party seeking to prove the invalidity of a patent must do so by clear and convincing evidence. *See Al-Site Corp. v. VSI Int'l, Inc.,* 174 F.3d 1308, 1323 [50 USPQ2d 1161] (Fed. Cir. 1999); *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH,* 139 F.3d 877, 881 [45 USPQ2d 1977] (Fed. Cir. 1998). Whenever possible, patent claims are to be interpreted in a manner that will uphold their validity. *See Whittaker Corp. v. UNR Indus., Inc.,* 911 F.2d 709, 712 [15 USPQ2d 1742] (Fed. Cir. 1990).

II. The '607 Patent

Based on the above legal standards, after considering all of the relevant evidence, I find that the '607 patent satisfies the definiteness requirement of Section 112. Based on the record before me, I conclude that a person of ordinary skill in the art would understand what is claimed in the patent, notwithstanding the absence of any specific definition or numerical quantification of the phrase, "does not substantially inhibit."

While the court has listened to and read relevant testimony from many witnesses, the parties' positions with respect to the definiteness of the phrase "does not substantially inhibit" were encapsulated by the testimony

of their two expert witnesses. Testifying on behalf of Alcon, Dr. Sean P. Gorman, a Professor of Pharmaceutical Microbiology at The Queen's University of Belfast in Northern Ireland, stated that neither the patent nor the file wrapper contained any definition of "does not substantially inhibit," or any information from which he could determine the meaning of that phrase. *See* Hearing Transcript, Vol. IV ("HT-IV") at 374-80. He stated that he himself had no understanding of what was meant by the phrase, HT-V at 403, and that "[i]t is a term that has no scientific meaning." HT-V at 404.

Dr. Gorman stated that in his opinion, the patent should have contained several items of information which are now missing, such as the types and numbers of microorganisms present during testing, and the duration of the tests. Absent such information, Dr. Gorman stated, one could not determine whether antimicrobial activity was considered to be "substantially inhibited."

B & L's expert witness was Dr. Barbara H. Iglewski, the Chair and Professor of Microbiology and Immunology at the University of Rochester. Dr. Iglewski, who holds a Ph.D. in Microbiology, is also the Chair of the Publications Board of the American Society for Microbiology, of which she is a Past President, and has authored or coauthored over 140 scholarly articles and books in her field. Dr. Iglewski has received numerous appointments and awards and held scores of positions over her distinguished 35 year career. (PTX 9).

Dr. Iglewski testified that in her opinion, the antimicrobial activity of a disinfecting solution would be "substantially inhibited" if it were reduced to a "microbiologically significant" extent. In her view, this would be determined by comparing the antimicrobial activity of the solution alone with that of the solution with a cleaning enzyme added. According to Dr. Iglewski, the measured reduction in antimicrobial activity after the addition of the enzyme would have to be greater than one log 2 for it to be microbiologically significant. The reason for this is that due to variables or errors that may occur in testing, the *actual* log order reduction is considered to be anywhere from 0.5 log above or below the *measured* log order. Thus, a measured 4-log reduction could in fact represent anywhere from a 3.5-log to a 4.5-log reduction. When comparing two different log order measurements, then, any difference between them of one log or less is not considered microbiologically significant, since the difference could be attributable to testing variables.

Dr. Gorman also recognized this principle, which he described as a "rule of thumb" in the field of microbiology. HT-V at 411. He opined, however, that if one were to equate "substantial" inhibition with "microbiologically significant" (*i.e.,* greater than one log) inhibition, the term "does not substantially inhibit" would make no sense. His reasoning was that any measured inhibition of one log or less is,

from the standpoint of a microbiologist, equivalent to no inhibition at all. Therefore, the smallest difference that a microbiologist would consider to show *any* inhibition at all would be a difference of just slightly higher than one log. In his view, that level of inhibition would be considered microbiologically significant, but not "substantial," which to him implied something greater than the smallest microbiologically significant difference. At what point along the continuum of log reductions an inhibition would become substantial he was unable to say, but in Dr. Gorman's view, a difference of, for example, 1.1 log would be considered small, not substantial. *See* HT-V at 413-15. In Dr. Gorman's opinion, then, if the patentees had meant that there was no *microbiologically significant* inhibition, they could have simply said that the enzyme "does not inhibit" the antimicrobial activity of the disinfectant, and left it at that. HT-V at 413-14.

I believe, however, that Dr. Iglewski's testimony adequately explained why this would not have been desirable. She testified that it would be possible, through repeated testing, to show that an inhibition of one log or less was actually occurring when the enzyme was added. Such an inhibition, she stated, might be considered *statistically* significant, but it would still not be *microbiologically* significant. Thus, a statistician examining test results that consistently showed a reduction in antimicrobial activity of 0.5 log might reach the conclusion that this difference could not be attributed to pure chance, and that indeed a real inhibition existed, but a microbiologist would still consider that difference not to be significant. HT-VI at 497.

I was persuaded by Dr. Iglewski's testimony that this is why it was proper to add a modifier, *i.e.* "substantially," to the verb "inhibit." Had the patentees said only that

the enzyme "does not inhibit" antimicrobial activity, a person skilled in the art might not know whether that meant literally no inhibition whatsoever, or simply no microbiologically significant inhibition. Contrary to Alcon's position, then, one skilled in the art would not consider a difference of exactly one log to be equal to zero, but simply not microbiologically *significant.* Likewise, one skilled in the art would not consider of difference of just over one log (*e.g.,* 1.1 log) to be minuscule or slight, but indeed significant. In fact, if the antimicrobial activity of a disinfectant is reduced by one log, that means that *ten times* as many microbes will be left living, and any reduction *greater* than that could certainly be deemed "substantial."

[2] Dr. Iglewski also testified that the word "substantially," as used in the '607 patent, was synonymous with "significantly." HT-IV at 500. This was consistent with much of the testimony at the hearing, which indicated that a person skilled in the art would want to know whether the addition of an enzyme reduced the antimicrobial activity of the disinfecting solution in a microbiologically significant way. The basic concept that a difference between two measurements of one log order or less is considered insignificant, because each of the two measurements could be off by plus or minus a half log, was repeated by many of the witnesses for both sides. *See, e.g.,* Testimony of David W. Proud, HT-II at 131 (stating that an inhibition becomes substantial " [w]hen it is outside the variability of the testing . . . about a one log range"); Testimony of Claude B. Anger, HT-III at 235-36 (stating that "anything within that area [of the range of testing variability] . . . is not considered meaningful"); Transcript of Thomas Riedhammer Deposition at 70 ("My general recollection of log reductions is that anything less than a log is within the error limits of the test"); Transcript of Katherine L. Shih Deposition at 91 (stating that a log reduction of less than 1.0 would not be a clear indication of disinfecting activity because " [w]e could have experimental error"); Transcript of Charles B. Slonim Deposition at 122 ("my understanding . . . would be that there is probably a half log value [range of testing error] on either side of the [measured] value . . . "); Transcript of Richard M. Kiral Deposition at 98 (stating that a difference of one log is " [n]ot considered significant in light of the errors typically associated with these kinds of tests"); Declaration of Alcon scientist Ruth Ann Rosenthal (PTX 33) 3 at 177-78 (stating that the addition of a cleaning enzyme to Alcon's Opti-Free disinfecting solution "did not produce a significant difference in disinfecting efficacy," and that "Opti-Free(Registered) maintained its original activity

(less than 1 log variability)"). The word "significant," like "substantial," is a relative term that does not inherently convey any particular quantifiable standard, yet all these witnesses indicated that they understood what it means, and that in the context of microbiology, a difference of one log or less is not considered significant.

Also supporting B & L's position are guidelines promulgated by the Food and Drug Administration ("FDA") in 1985 ("the 1985 Guidelines"). Although they are characterized as "draft" guidelines, the parties do not dispute that in fact they were followed throughout the contact lens industry, and that they were in effect at the time of B & L's patent application that led to the issuance of the '607 patent. Among other things, the 1985 Guidelines provide that

A manufacturer may, for a variety of reasons, want to make changes in the formulation of a previously approved solution . . . . In the case of a solution modification, the manufacturer should be prepared to demonstrate to FDA that changes in the formulation do not adversely affect the performance characteristics of the original approved solution.

DTX 47 at 23.

A number of witnesses testified that a company seeking to market a new enzymatic cleaner that could be used in a one-step process with a disinfecting solution would want to ensure that it could obtain FDA approval for the product. *See, e.g.* , Shih Depo. at 134 ("when we decide to select what will be commercialized, we have to consider the FDA guidelines to pass the guidelines"); VanDuzee Depo. at 418 ("What we [at Alcon] were attempting to do was to define a standard which we thought that we needed to achieve in order to gain FDA approval for a product"); *Modern Pharmaceutics* (PTX 82) at 597 (stating that 1985 guidelines "have a major impact on how manufacturers develop lens care products"; coauthored by Alcon Vice President Barry F. VanDuzee). Certainly it would make little sense to invest much time or money in developing a product if the company did not think it had a reasonable chance of obtaining FDA approval.

Although the 1985 Guidelines do not expressly define "do not adversely affect," the natural interpretation to be given that phrase would seem to be that, in the context of a modified disinfecting system, the changes do not reduce the disinfectant's antimicrobial activity. Coupled with the testimony that from the standpoint of a microbiologist, reduction of such activity is not considered significant unless the difference between systems with and without enzyme present is greater than one log, this leads me to conclude that one skilled in the art would understand that in order to obtain FDA approval, one would have to be prepared to show that the addition of the enzyme does not produce a level of inhibition exceeding one log order of performance.

[3] Moreover, although the '607 patent does not expressly link the term "does not substantially inhibit" to the 1985 Guidelines, the evidence indicates that persons of ordinary skill in the art would understand that the '607 patent is directed to a cleaning and disinfecting solution intended for commercialization, which would require prior FDA approval. The logical inference to be drawn, then, is that the patent's statement that the addition of the enzyme "does not substantially inhibit" the antimicrobial activity of the disinfectant embodies the notion that it does not "adversely affect" the disinfectant's performance, as required by the 1985 Guidelines. For example, David Proud, a B & L scientist and one of the inventors named on the '607 patent, testified that in his opinion, microbiologists reading the '607 patent, in light of the 1985 Guidelines, "would understand that we are talking about not adversely affecting the disinfecting solution . . . ." HT-II at 150. Likewise, Dr. Iglewski stated that "adversely affected" and "substantially inhibited" were "interchangeable," and that if the claim in the '607 patent had said, "which does not adversely affect the activity," it would mean the same thing that it does now. HT-VI at 505. Joy T. Barnitz, who was a B & L Technical Expert from 1991 to 1997, also testified at her deposition that those of ordinary skill in the art knew that to obtain FDA approval, it was necessary to show the antimicrobial activity of the solution "was not adversely affected--substantially inhibited . . ."

when the enzyme was added. Transcript of Joy T. Barnitz Depo. at 164.
Indeed, one of Alcon's own witnesses, Claude B. Anger, the Director of Pharmaceutical Microbiology at Allergan, Inc., which also develops and markets contact lens products, though stating that he did not know what the term "does not substantially inhibit" means in the '607 patent, admitted on cross-examination that several of Allergan's own patents, including some on which Anger himself was named as an inventor, use similar language. For example, United States Patent No. 5,515,117, on which Anger is named, uses the words "substantial" and "substantially" dozens of times in a variety of contexts: "substantially non-leachable"; "substantially all . . . of the microorganisms"; "substantially metal-free"; "substantially uniformly distributed"; "substantially the total . . . amount of antimicrobial activity"; and so on. PTX 75. At the hearing, after reviewing the patent, Anger conceded that the patent did not contain any definition of "substantially," and that the word was not quantified anywhere in the patent. HT-III at 252.
Similarly, United States Patent No. 5,736,165, on which Anger was also named as an inventor, uses the phrases, "substantially isotonic," "no substantial detrimental effect," "substantially free of any activator," "substantially stationary," "substantially alleviated," and "substantially free of any component or residue thereof." PTX 76. Again, Anger testified that these terms were not quantified anywhere in the patent. HT-III at 253.
Another of Anger's patents, No. 5,660, 862, likewise contained numerous uses of the word "substantially": "substantially isotonic"; "substantially free of peroxidase"; "to destroy substantially all the hydrogen peroxide"; "at substantially the same time"; "no substantial detrimental effect"; "with substantially no hydrogen peroxide present"; "substantially surrounds the coated portion"; "to substantially eliminate hydrogen peroxide"; "substantially no release occurs"; "effects removal . . . of substantially all of at least one type of debris"; "are substantially the same"; "substantially no humidity"; "substantially liquid"; " [s]ubstantially all of the protein-based debris is removed"; and others. PTX 77. Once again, Anger stated that he did not believe that the word "substantially" was quantified anywhere in the patent. HT-III at 254.
There was also evidence that Alcon itself has used the word "substantially" in its own patents and in proceedings before the Patent and Trademark Office ("PTO"). Dr. Barry F. VanDuzee, Alcon's Vice President of International Development, who holds a Ph.D. in physical chemistry, testified on cross-examination by counsel for B & L concerning a declaration that he had submitted to the PTO in April 1995, relating to a pending patent application that had been filed by Alcon. In the declaration, VanDuzee stated

that he and his coinventor, Ruth Ann Rosenthal, had sought to develop a method for simultaneously cleaning and disinfecting contact lenses such that the combined solution "had substantially the same level of, if not better, antimicrobial activity as the disinfecting solution alone." PTX 26 Para. 5. Dr. VanDuzee testified that to him, "substantially the same" meant "little or no difference." HT-IV at 339.
B & L also introduced into evidence a patent application filed by Alcon in September 1991. This application states that it "relates to methods and compositions for the simultaneous cleaning and disinfecting of human-worn contact lenses." PTX 33 at 82. In February 1993, Alcon amended the application to add language in Claim 1 stating that the cleaning enzyme "does not substantially inhibit the disinfecting activity of the [antimicrobial agent] when the two components are combined." *Id.* at 168. The amendment went on to say that "Claim 1 has also been amended in order to *clarify* that the present invention comtemplates no *significant* loss of disinfecting effectiveness of the presently claimed compositions, as compared to the disinfecting solution used alone." *Id.* at 169 (emphasis added).
Although Alcon contends that this language was added to the application in order to provoke an interference with the '607 patent, the fact remains that on its face, Alcon's amendment declares that the "does not substantially inhibit" language was added to *clarify* the nature of the invention. The

amendment also appears to equate "substantial" with "significant," which is consistent with Dr. Iglewski's testimony that as substantial inhibition is one that she would consider microbiologically significant.

In addition, in a different application, Alcon did copy B & L's claims to provoke an interference with the '607 patent. *See* PTX 7 at 10. In that application, however, Alcon said that its proposed count stated "that the osmotic value must be at a level which does not substantially inhibit the activity of the antimicrobial agent. However *both* parties *support* this limitation of the count." *Id.* at 40 (emphasis added).

[4] This evidence, then, indicates that the use of the words "substantial" and "substantially" in patents is not uncommon in the contact lens industry. I also note that one phrase in one of Anger's patents, "no substantial detrimental effect," conveys a similar idea as "does not substantially inhibit": that no "substantial" adverse effect occurs.

[5] In addition to the testimony of its own witnesses, Alcon, as it did in its summary judgment motion, relies on alleged inconsistencies in the testimony of B & L's witnesses. After listening to and reading this testimony, I am no more persuaded now than I was in my summary judgment decision that there are any significant inconsistencies in that testimony that would warrant a finding of indefiniteness. Some witnesses may at various times have used different words to explain their understanding of "does not substantially inhibit," but that does not necessarily make their testimony inconsistent or self-contradictory. A witness need not repeat prior testimony verbatim to maintain a consistent position, and I find that the alleged inconsistencies pointed to by Alcon are insubstantial and based in large part on testimony being taken out of context.

Alcon also asks the court to consider certain materials submitted by B & L to the European Patent Office ("EPO"), and the EPO's decision, with respect to a European counterpart to the '607 patent. In particular, Alcon relies on an amendment to the European patent application in which B & L set forth specific log reduction values against a particular microbe. B & L contends that these materials are irrelevant and inadmissible.

[6] I find it unnecessary to determine whether these documents are admissible in this action, because even if I were to consider them, they would not alter the result here. At most, they merely indicate the B & L might have been able to couch the claims of the '607 patent in terms of actual numerical values rather than by using the term of degree, "does not substantially inhibit." As stated however, " [m]athematical precision should not be imposed for its own sake; a patentee has the right to claim the invention in terms that would be understood by persons of skill in the field of the invention." *Modine* , 75 F.3d at 1557. Just becuase a claim *can* be expressed in numerical terms, then, does not mean that it *must* be. The Federal Circuit has observed that " [c]laims are often drafted using terminology that is not as precise or specific as it *might* be," but that is perfectly permissible as long as the patent complies with the requirement of Section 112 Para. 2 that it particularly point out and distinctly claim the subject matter which the applicant regards as his invention. *PPG* , 156 F.3d at 1355 (emphasis added). Regardless of whether B & L could have chosen to use language in the '607 patent comparable to that in its European application, I find that the '607 patent meets the definiteness requirement of Section 112. As stated earlier, the burden here is on Alcon to prove the invalidity of the '607 patent by clear and convincing evidence. *Al-Site* ,

174 F.3d at 1323. In addition, if a claim can reasonably be interpreted in a way that will uphold its validity, the court should do so. *Whittaker* , 911 F.2d at 712. After considering all the evidence, I find that Alcon has failed to carry its burden.

I also note that, although in reaching my conclusion that the '607 patent is not indefinite, I have relied to some extent on the testimony of B & L's witnesses concerning their interpretation of the claims of the patent, I have done so only with respect to the issue of indefiniteness. Nothing in this Decision and Order should be viewed as expressing a ruling on what the claims actually mean or how they should be

construed. That issue will be addressed following the *Markman* hearing that is currently scheduled to begin on January 10, 2000.

CONCLUSION

Defendant Alcon Laboratories, Inc.'s request for entry of judgment that the claims of the '607 patent are indefinite under 35 U.S.C. Section 112 is denied.
IT IS SO ORDERED.

Footnotes

Footnote 1. Although Alcon contends that all of these cases are distinguishable from the case at bar, they nonetheless do establish that the use of terms of degree such as "substantially" does not in itself render a claim indefinite.
Footnote 2. The term "log" or "log order" refers to the use of a logarithm to the base 10 to measure antimicrobial activity. Thus, a 90% reduction of the presence of a particular microbe would a be 1-log reduction, a 99% reduction would be a 2-log reduction, a 99.9% reduction would be a 3-log reduction, and so on. A reduction from 3 logs to 2, then (*i.e.* from 99.9% to 99%) would constitute a difference of one log order in performance.
Footnote 3. Defendant's and Plaintiff's exhibits introduced at the hearing are respectively designated as "DTX" and "PTX."

- End of Case -

ISSN 1526-8535